AWARD NUMBER: W81XWH-16-2-0013

TITLE: Trauma Outcomes and UroGenital Health in OEF/OIF (TOUGH) - A Retrospective Cohort Study with Long-Term Follow-up

PRINCIPAL INVESTIGATOR: Bradley H. Pollock, PhD MPH

CONTRACTING ORGANIZATION: University of California, Davis
Davis, CA 95616

REPORT DATE: July -2017

TYPE OF REPORT: ANNUAL

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
JUL-2017	ANNUAL	1 Jul 2016 - 30 Jun 2017

4. TITLE AND SUBTITLE

Trauma Outcomes and UroGenital Health in OEF/OIF (TOUGH) - A Retrospective Cohort Study with Long-Term Follow-up

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-16-2-0013

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

POLLOCK, BRADLEY H.

E-Mail: BPOLLOCK@UCDAVIS.EDU

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

UNIVERSITY OF CALIFORNIA, DAVIS
1850 RESEARCH PARK DR, STE 300
DAVIS CA 95618-6134

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

Enter a brief (approximately 200 words) unclassified summary of the most significant finding during the research period.

There have been three peer-reviewed three publications to date: 1) Nnamani NS, Janak JC, Hudak SJ, Rivera JC, Lewis EA, Soderdahl DW, Orman JA. *J Trauma Acute Care Surg*. 2016 (5 Suppl 2 Proceedings 2015 Military Health System Research Symposium):S95-S99; 2) Janak JC, Orman JA, Soderdahl DW, Hudak SJ. *J Urol.* 2017;197(2):414-419; and 3) Nnamani NS, Janak JC, Hudak SJ, Rivera JC, Lewis EA, Soderdahl DW, Orman JA. *J Trauma Acute Care Surg*. 2016.

For U.S. male service members who served in OEF/OIF from 10/ 2001 to 8/2013, 1,367 sustained ≥1 or more genitourinary injuries; the majority involved the external genitalia (n=1,000, 73.2%), including the scrotum (760, 55.6%), testes (451, 33.0%), penis (423, 31%) and/or urethra (125, 9.1%) There was a high frequency of concomitant GU injury and extremity amputation which has serious implications for health and quality of life presenting to prevent, mitigate, and treat these battlefield injuries.

15. SUBJECT TERMS Key words or phrases identifying major concepts in the report.
Genitourinary injury; epidemiology; urotrauma

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER *(include area code)*
Unclassified	Unclassified	Unclassified	Unclassified	6	USAMRMC

TABLE OF CONTENTS

INTRODUCTION

This goal of this study is to identify the characteristics of service members, their genitourinary injuries, the care received for these injuries, and other factors that predict long-term outcomes. The knowledge gained will help optimize acute injury treatment planning as well as help inform development of more effective long-term care strategies.

KEY WORDS

Genitourinary injury; epidemiology; urotrauma

ACCOMPLISHMENTS

Goals:

The major goals of this project are: 1) Using a cohort design, estimate the incidence of adverse outcomes and identify prognostic factors including comorbid injuries that predict poor long-term outcomes; 2) Using a patient-centered approach, describe the natural history of recovery from GU injuries based on patient-reported outcome measures obtained via an annual health survey; and 3) Investigate the physiologic impairments and associated adverse outcomes based on an in- person physical examination (for a local subset of the study population).

Progress:

There have been three peer-reviewed three publications to date:

1. Nnamani NS, Janak JC, Hudak SJ, Rivera JC, Lewis EA, Soderdahl DW, Orman JA. *J Trauma Acute Care Surg*. 2016 (5 Suppl 2 Proceedings 2015 Military Health System Research Symposium):S95-S99
2. Janak JC, Orman JA, Soderdahl DW, Hudak SJ. *J Urol.* 2017;197(2):414-419
3. Nnamani NS, Janak JC, Hudak SJ, Rivera JC, Lewis EA, Soderdahl DW, Orman JA. *J Trauma Acute Care Surg*. 2016.

For U.S. male service members who served in OEF/OIF from 10/ 2001 to 8/2013, 1,367 sustained ≥1 or more genitourinary injuries; the majority involved the external genitalia (n=1,000, 73.2%), including the scrotum (760, 55.6%), testes (451, 33.0%), penis (423, 31%) and/or urethra (125, 9.1%) There was a high frequency of concomitant GU injury and extremity amputation which has serious implications for health and quality of life presenting to prevent, mitigate, and treat these battlefield injuries.

During the reporting period (01 July 2016 to 30 June 2017), several key milestones have been achieved. Subcontract funding for the University of Texas Health Science Center at San Antonio (now called UT Health San Antonio) has been initiated. The study team has held several face-to-face meetings to work out the logistics of phase 2 of the protocol. The External Advisory Board membership has been established. The study team developed the modified study protocol, consent documents, and institutional application for submission to the University of California Davis (UT Davis) and UT Health San Antonio Institutional Review Boards (IRBs). The study team has achieved the Task 1 Milestone, obtaining IRB approval, on June 13, 2017. Both the UC Davis and the UT Health San Antonio IRBs approved the study via Expedited Review and deemed the study minimal risk. The UC Davis and UT Health San Antonio study team has worked in coordination with study personnel from the U.S. Army Institute for Surgical Research (USAISR) to develop the initial draft of the survey administration protocol, chart abstraction protocol, and chart abstraction data form to confirm eligibility of cases via record abstraction. In addition, the first draft of the study questionnaire was developed and is under review by subject matter experts.

The patient roster was obtained list from the Department of Defense Trauma Registry (DoDTR) and we are hiring a contractor who will conduct the chart abstractions at Brooke Army Medical Center (BAMC). The purpose of this is to confirm eligibility of cases via record abstraction. We are working to refine the physical examination case report forms and the primary study survey questionnaire. In addition we are developing the

accrual monitoring reports, study electronic case report forms (eCRFs) to implement the survey, and a comprehensive study GU Injury Database with a complete data dictionary.

UT Health San Antonio is also working to obtain approval of the study from the USAMRMC Office of Research Protections (ORP) Human Research Protections Office (HRPO) for the UT Health San Antonio site which will be doing direct contact with study subjects, as required.

Opportunities for Training and Professional Development

Nothing to report

Dissemination to Communities of Interest

Nothing to report

Plans for the next reporting period

1. Finalize questionnaire for the initial patient survey.
2. Convene a face-to-face meeting of our TOUGH External Advisory Committee in the Fall 2017 to finalize the phase 2 protocol.
3. Begin accrual in this grant year.

IMPACT

The incidence and characteristics of GU injuries treated in Operation Iraqi Freedom/Operation Enduring Freedom (OIF/OEF) have been described in recent literature. However, the information about care received and needed and lasting morbidity from these injuries has yet to be described. The information obtained from this study will ensure that wounded warriors have and are receiving the care required for their injuries. The information will be used to guide military leadership to ensure programs are in place to better serve SMs with GU injuries.

Care for returning SMs is and will be a lasting duty that is entrusted to all healthcare providers in the Departments of Defense and Veterans Affairs. Ensuring that those who have served receive all necessary care is paramount to this duty. The initial treatment in theatre may have been temporizing or definitive. However, the lasting impact is unknown and patterns of healthcare utilization and unmet needs for care for the outcomes of GU injury are also unknown. Identifying the group of SMs with lower/external GU injuries and asking them about their health status and healthcare needs will allow us to ensure that they have received and are receiving proper care as well as identify changes over time. Because some of the SMs in our study will have been injured more than 10 years ago during the early years of the war, we will have very long-term outcome data (i.e., 20 years or more) on a subset of the participants in this study.

CHANGES/PROBLEMS

The Human Research Protections (HRP) Administrator at BAMC recently declined to approve the USAISR site's protocol amendment request to add Dr. Pollock and Dr. Pugh as associate investigators to the BAMC protocol and to add UT Health San Antonio as additional study site. According to the BAMC IRB, since UT Health San Antonio is performing most of the study activities (direct subject contact and data collection) the BAMC IRB should defer to the UT Health San Antonio IRB. As a result, UT Health San Antonio is coordinating with the USAISR to prepare all documents necessary to request a deferral to the UT Health San Antonio IRB as allowed by the USAISR/UTHSA IRB reciprocity agreement.

The BAMC IRB recommended that a new protocol be developed for the Phase 2 portion of the study (versus amending the current protocol which contained phase 1 and Phase 2 components) and that the new protocol be submitted to the UT Health San Antonio IRB. We are writing the new Phase 2 protocol document which will: (i) describe procedures for a new MOA with the Joint Trauma System (JTS); and (ii) specify the plan for how the study staff will access the DoD data sources for abstraction purposes.

Although the BAMC IRB previously approved the Phase 2 study, according to the BAMC IRB HRP Administrator, Phase 2 cannot commence until the new Phase 2 protocol is reviewed and approved at all relevant institutions. As a result, we are directing our efforts to prepare this new Phase 2 protocol that addresses all of the previously noted changes.

In addition to the protocol changes, the USAISR on-site PI is no longer USAISR staff and is currently meeting with USAISR leadership and USAISR Research and Regulatory to determine whether an ISR investigator must be assigned to the study.

There are no significant changes in use of care of human subjects, vertebrate animals, biohazards, and/or select agents.

PARTICIPANTS AND OTHER COLLABORATING ORGANIZATIONS DURING THE REPORTING PERIOD

University of California, Davis
Brad H. Pollock, PhD, MPH (PI)

University of Texas Health, San Antonio
Mary Jo Pugh, PhD, RN (Site PI)
Hari Sagiraju MD, PhD (Research Assistant)
Barbara Elizondo, RAS Senior (Research Assistant)
Bill Sanns, (Project Operations Director)

SPECIAL REPORTING REQUIREMENTS

None

APPENDICES

None